

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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|                                 |   |                       |
|---------------------------------|---|-----------------------|
| JAZZ PHARMACEUTICALS, INC.,     | ) |                       |
|                                 | ) |                       |
| Plaintiff,                      | ) |                       |
|                                 | ) |                       |
| v.                              | ) | C.A. No. 21-691 (GBW) |
|                                 | ) |                       |
| AVADEL CNS PHARMACEUTICALS LLC, | ) |                       |
|                                 | ) |                       |
| Defendant.                      | ) |                       |

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|---------------------------------|---|------------------------|
| JAZZ PHARMACEUTICALS, INC. and  | ) |                        |
| JAZZ PHARMACEUTICALS IRELAND    | ) |                        |
| LIMITED,                        | ) |                        |
|                                 | ) |                        |
| Plaintiffs,                     | ) |                        |
|                                 | ) |                        |
| v.                              | ) | C.A. No. 21-1138 (GBW) |
|                                 | ) |                        |
| AVADEL CNS PHARMACEUTICALS LLC, | ) |                        |
|                                 | ) |                        |
| Defendant.                      | ) |                        |

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|---------------------------------|---|------------------------|
| JAZZ PHARMACEUTICALS, INC. and  | ) |                        |
| JAZZ PHARMACEUTICALS IRELAND    | ) |                        |
| LIMITED,                        | ) |                        |
|                                 | ) |                        |
| Plaintiffs,                     | ) |                        |
|                                 | ) |                        |
| v.                              | ) | C.A. No. 21-1594 (GBW) |
|                                 | ) |                        |
| AVADEL CNS PHARMACEUTICALS LLC, | ) |                        |
|                                 | ) |                        |
| Defendant.                      | ) |                        |

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## **1. GENERAL INSTRUCTIONS**

### **1.1 INTRODUCTION**

Members of the jury, now it is time for me to instruct you about the law that you must follow in deciding this case. Each of you has been provided a copy of these instructions. You may read along as I deliver them if you prefer.

I will start by explaining your duties and the general rules that you must use in evaluating the testimony and evidence. Then I will explain the positions of the parties and the law you will apply in this case. And last, I will explain the rules that you must follow during your deliberations in the jury room, and the possible verdicts that you may return.

Please listen very carefully to everything I say.

You will have a written copy of these instructions with you in the jury room for your reference during your deliberations. You will also have a verdict form, which will list the questions that you must answer to decide this case.

## **1.2 JURORS' DUTIES**

You have two main duties as jurors. The first is to decide what the facts are from the evidence that you saw and heard in court. Deciding what the facts are is your job, not mine, and nothing that I have said or done during this trial was meant to influence your decision about the facts in any way. You are the sole judges of the facts.

Your second duty is to take the law that I give you, apply it to the facts, and decide under the appropriate burden of proof which party should prevail on any given issue. It is my job to instruct you about the law, and you are bound by the oath you took at the beginning of the trial to follow the instructions that I give you, even if you personally disagree with them. This includes the instructions that I gave you before and during the trial, and these instructions. All of the instructions are important, and you should consider them together as a whole.

Perform these duties fairly. Do not guess or speculate, and do not let any bias, sympathy, or prejudice you may feel toward one side or the other influence your decision in any way.

### **1.3 EVIDENCE DEFINED**

You must make your decision based only on the evidence that you saw and heard here in court. Do not let rumors, suspicions, or anything else that you may have seen or heard outside of court influence your decision in any way. The evidence in this case includes only what the witnesses said while they were testifying under oath, including deposition transcript testimony that has been played by video or read to you, the exhibits that I allowed into evidence, matters I have instructed you to take judicial notice of, and the stipulations to which the lawyers agreed.

Certain charts, summaries, and graphics have been used to illustrate certain evidence and testimony from witnesses. Unless I have specifically admitted them into evidence, these charts, summaries, and graphics are not themselves evidence, even if they refer to, identify, or summarize evidence, and you will not have these demonstratives in the jury room.

Nothing else is evidence. The lawyers' statements and arguments are not evidence. The arguments of the lawyers are offered solely as an aid to help you in your determination of the facts. Their questions and objections are not evidence. My legal rulings are not evidence. You should not be influenced by a lawyer's objection or by my ruling on that objection. Any of my comments and questions are not evidence.

During the trial I may have not let you hear the answers to some of the questions that the lawyers asked. I also may have ruled that you could not see some of the exhibits that the lawyers wanted you to see. And, sometimes I may have ordered you to disregard things that you saw or heard, or that I struck from the record. Those things are not evidence. You must make your decision only based on the evidence, as I have defined it, and nothing else.

#### **1.4 DIRECT AND CIRCUMSTANTIAL EVIDENCE**

During the preliminary instructions, I told you about “direct evidence” and “circumstantial evidence.” I will now remind you what each means.

Direct evidence is simply evidence like the testimony of an eyewitness which, if you believe it, directly proves a fact. If a witness testified that he saw it raining outside, and you believe him, that would be direct evidence that it was raining.

Circumstantial evidence is simply a chain of circumstances that indirectly proves a fact. If someone walked into the courtroom wearing a raincoat covered with drops of water and carrying a wet umbrella, that would be circumstantial evidence from which you could conclude that it was raining.

It is your job to decide how much weight to give the direct and circumstantial evidence. The law makes no distinction between the weight that you should give to either one, nor does it say that one is any better evidence than the other. You should consider all the evidence, both direct and circumstantial, and give it whatever weight you believe it deserves.

### **1.5 CONSIDERATION OF EVIDENCE**

You should use your common sense in weighing the evidence. Consider it in light of your everyday experience with people and events, and give it whatever weight you believe it deserves. If your experience tells you that certain evidence reasonably leads to a conclusion, you are free to reach that conclusion.



## **1.6 AGENCY**

Jazz and Avadel are corporations and can only act through their officers and employees. Any action or omission of an officer or employee within the scope of his or her employment is the action or omission of the corporation that employs him or her.

### **1.7 STATEMENTS OF COUNSEL**

A further word about statements of counsel and arguments of counsel. The attorneys' statements and arguments are not evidence. Instead, their statements and arguments are intended to help you review the evidence presented. If you remember the evidence differently from the way it was described by the attorneys, you should rely on your own recollection.

### **1.8 FACTS ADMITTED**

Certain facts that the parties have admitted during the course of this case have been read to you during this trial. You must treat these facts as having been proved for purposes of this case.

## **1.9 CREDIBILITY OF WITNESSES**

You are the sole judges of each witness's credibility. You may believe everything a witness says, or part of it, or none of it. You should consider each witness's means of knowledge; strength of memory; opportunity to observe; how reasonable or unreasonable the testimony is; whether it is consistent or inconsistent; whether it has been contradicted; the witness's biases, prejudices, or interests; the witnesses' manner or demeanor on the witness stand; and all circumstances that, according to the evidence, could affect the credibility of the testimony.

In determining the weight to give to the testimony of a witness, you should ask yourself whether there was evidence tending to prove that the witness testified falsely about some important fact, or, whether there was evidence that at some other time the witness said or did something, or failed to say or do something, that was different from the testimony he gave at the trial by deposition testimony played by video. You have the right to distrust such a witness's testimony and you may reject all or some of the testimony of that witness or give it such credibility as you may think it deserves.

You should remember that a simple mistake by a witness does not necessarily mean that the witness was not telling the truth. People may tend to forget some things or remember other things inaccurately. If a witness has made a misstatement, you must consider whether it was simply an innocent lapse of memory that they remembered better on reconsideration or an intentional falsehood, and that may depend upon whether it concerns an important fact or an unimportant detail.

### **1.10 EXPERT WITNESSES**

Expert testimony is testimony from a person who has a special skill or knowledge in some science, profession, or business. This skill or knowledge is not common to the average person but has been acquired by the expert through special study or experience.

In weighing expert testimony, you may consider the expert's qualifications, the reasons for the expert's opinions, and the reliability of the information supporting the expert's opinions, as well as the factors I have previously mentioned for weighing testimony of any other witness. Expert testimony should receive whatever weight and credit you think appropriate, given all the other evidence in the case. You are free to accept or reject the testimony of experts, just as with any other witness.

### **1.11 DEPOSITION TESTIMONY**

During the trial, certain testimony was presented to you by the playing of video excerpts from a deposition. The deposition testimony may have been edited or cut to exclude irrelevant testimony as the parties have only a limited amount of time to present you with evidence. You should not attribute any significance to the fact that the deposition videos may appear to have been edited.

Deposition testimony is out of court testimony given under oath and is entitled to the same consideration you would give it had the witnesses personally appeared in court.

### **1.12 NUMBER OF WITNESSES**

One more point about the witnesses. Sometimes jurors wonder if the number of witnesses who testified makes any difference.

Do not make any decisions based only on the number of witnesses who testified. What is more important is how believable the witnesses were, and how much weight you think their testimony deserves. Concentrate on that, not the numbers.

### **1.13 EXHIBITS**

During the course of the trial, you have seen many exhibits. Many of these exhibits were admitted as evidence. You will have these admitted exhibits in the jury room to consider as evidence for your deliberations.

The remainder of the exhibits (including charts, graphics, Power Point presentations, and animations) were offered to help illustrate the testimony of the various witnesses. These illustrative exhibits, called “demonstrative exhibits,” will not be in the jury room and have not been admitted, are not evidence, and should not be considered as evidence. Rather, it is the underlying testimony of the witness that you heard when you saw the demonstrative exhibits that is the evidence in this case.



#### **1.14 USE OF NOTES**

You may have taken notes during trial to assist your memory. As I instructed you at the beginning of the case, you should use caution in consulting your notes. There is generally a tendency to attach undue importance to matters which one has written down. Some testimony which is considered unimportant at the time presented, and thus not written down, takes on greater importance later in the trial in light of all the evidence presented. Therefore, your notes are only a tool to aid your own individual memory, and you should not compare notes with other jurors in determining the content of any testimony or in evaluating the importance of any evidence. Your notes are not evidence, and are by no means a complete outline of the proceedings or a list of the highlights of the trial.

Above all, your memory should be the greatest asset when it comes time to deliberate and render a decision in this case.

### **1.15 BURDENS OF PROOF**

In any legal action, facts must be proven by a required standard of evidence, known as the “burden of proof.” In a case involving patents, two different burdens of proof are used. The first is a lower burden called “preponderance of the evidence.” The second is a higher burden called “clear and convincing evidence.” I told you about these standards of proof during my preliminary instructions to you and I will now remind you what they mean.

Jazz has accused Avadel of infringing certain claims of two patents. Avadel denies infringement for the '488 patent but admits infringement for the '782 patent. Avadel also contends that the asserted claims are invalid.

Jazz bears the burden of proving infringement and the amount of monetary damages by a preponderance of the evidence. Preponderance of the evidence is evidence that is more likely true than not. To put it another way, if you were to put Jazz’s and Avadel’s evidence on opposite sides of the same scale, and the evidence supporting Jazz’s claims would make the scale tip to Jazz’s side, then you should find for Jazz. If the scale should remain equal or tip somewhat to Avadel’s side, then Jazz has not met its burden of proof.

Avadel bears the burden of proving that each of the asserted claims is invalid and must do so by clear and convincing evidence. Clear and convincing evidence means evidence that it is highly probable that a fact is true. Proof by clear and convincing evidence is a higher standard of proof than proof by a preponderance of the evidence.

You may have heard of the term "proof beyond a reasonable doubt" from criminal cases. That requirement is the highest burden of proof in our judicial system. It applies only in criminal cases and has nothing to do with a civil case like this one. You should therefore not consider that burden of proof in this case.

## **2. THE PARTIES AND THEIR CONTENTIONS**

### **2.1 THE PARTIES**

I will now review for you the parties in this action, and the positions of the parties that you will have to consider in reaching your verdict.

As I have previously told you, the plaintiffs in this case are Jazz Pharmaceuticals Incorporated and Jazz Pharmaceuticals Ireland Limited. We have referred to the plaintiffs together as Jazz. The defendant in this case is Avadel CNS Pharmaceuticals. We have referred to the defendant as Avadel.

Plaintiff Jazz is the owner of the two patents at issue in this case: United States Patent Nos. 10,758,488 and 11,147,782. You have heard the lawyers and the witnesses in the case refer to these patents by their last three numbers—the '488 patent and the '782 patent. Sometimes we referred to them collectively as the asserted patents or patents-in-suit.

## **2.2 THE PARTIES' CONTENTIONS**

Jazz contends that Avadel has infringed the asserted claims and that it is entitled to damages for Avadel's past infringement of those asserted claims.

Avadel denies that it infringes two limitations of the '488 patent, which the parties have referred to as the "core" and the "deionized water" limitations. Avadel admits infringement of the '782 patent. Avadel also contends that each asserted claim is invalid for one or more of the following reasons, which will be explained further below: lack of written description, lack of enablement, derivation, and/or improper inventorship. Avadel also denies that Jazz is entitled to recover past damages related to the patents.

I will now summarize the patent issues that you must decide and for which I will provide instructions to guide your deliberations. The specific questions you must answer are listed on the verdict sheet you will be given. Here are the issues you must decide:

- Whether Jazz has proven by a preponderance of the evidence that Avadel has infringed claim 7 of the '488 patent.
- Whether Jazz has proven by a preponderance of the evidence that Avadel has infringed claim 11 of the '488 patent.
- Whether Avadel has proven by clear and convincing evidence that claim 7 of the '488 patent is invalid.
- Whether Avadel has proven by clear and convincing evidence that claim 11 of the '488 patent is invalid.
- Whether Avadel has proven by clear and convincing evidence that claim 24 of the '782 patent is invalid.
- If you decide that Avadel has infringed any asserted claim of a patent-in-suit that is not invalid, you will also need to decide any money damages to be awarded to Jazz to compensate Jazz for that past infringement. That decision will include both whether Jazz has proven by a preponderance of the evidence that it is entitled to damages as well as the amount of damages for past infringement.

I will provide more detailed instructions on each of the issues you must decide elsewhere in these jury instructions.

### **3. PATENT INFRINGEMENT CLAIMS**

#### **3.1 THE PATENT LAWS**

At the beginning of the trial, I gave you some general information about patents and the patent system and a brief overview of the patent laws relevant to this case. I will now give you more detailed instruction about the patent laws that specifically relate to this case. If you would like to review my instructions at any time during your deliberations, you will have your copy available to you in the jury room.

### **3.2 PATENT “CLAIMS” GENERALLY**

Before you can decide many of the issues in this case, you will need to understand the role of patent “claims.” The patent claims are the numbered paragraphs at the end of each patent. Everything before the claims in the numbered paragraphs is referred to as the “specification.” The claims are important because it is the words of the claims that define what a patent covers. Only the claims of a patent can be infringed.

The claims are intended to define, in words, the bounds of an invention. The text in the rest of the patent provides a description of the invention and provides context for the claims, but it is the claims that define what the patent covers. Each of the asserted claims must be considered individually.

In patent law, the requirements of a claim are often referred to as “claim elements” or “claim limitations.” For example, a claim that covers the invention of a table may recite the tabletop, four legs, and the glue that secures the legs to the tabletop. The tabletop, legs, and glue are each separate limitations of the claim. When a thing (such as a product) meets each and every requirement of a claim, the claim is said to “cover” that thing, and that thing is said to “fall” within the scope of that claim.

One claim may cover more or less than another claim. Therefore, what a patent covers depends, in turn, on what each of its claims covers.

You will first need to understand what each claim covers in order to decide whether there is infringement of the claim and to decide whether the claim is invalid. You must use the same claim meaning for both your decision on infringement and your decision on invalidity.

### 3.3 CONSTRUCTION OF THE CLAIMS

It is the Court's duty under the law to define what the words in the patent claims mean. As I instructed you at the beginning of the case, I have made my determinations, and I will now instruct you on the meaning, or "construction," of the claim terms. You must apply the meaning that I give in each patent claim to decide if the claim is infringed or invalid. You must accept my definitions of these words in the claims as being correct. You must ignore any different definitions used by the witnesses or the attorneys.

You are advised that the following definitions for the following terms must be applied:

| Claim Term   | Construction   |
|--|--|
| "sustained release portion"<br>'488 patent         | Plain and ordinary meaning, i.e., the portion of the formulation that is not immediate release and that releases over a period of time   |
| "by about 4 to about 6 hours"<br>'488 patent       | Plain and ordinary meaning, which is at any point prior to approximately 4 hours or at any point prior to approximately 6 hours  |
| "gamma-hydroxybutyrate"<br>'488 patent             | Plain and ordinary meaning: i.e., (1) gamma-hydroxybutyric acid or (2) the negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid                    |
| "modified release particles"<br>'782 patent        | Plain and ordinary meaning, i.e., particles containing an active pharmaceutical ingredient with a release profile that is different from that of an immediate release particle |
| "gamma-hydroxybutyrate" / "oxybate"<br>'782 patent | The negatively charged or anionic form (conjugate base) of gamma-hydroxybutyric acid   |

For any words in a claim for which I have not provided you with a definition, you should apply the plain and ordinary meaning to a person of ordinary skill in the art.



### **3.4 INDEPENDENT AND DEPENDENT CLAIMS**

Patents have two types of claims: independent claims and dependent claims.

An independent claim does not refer to any other claim of the patent and sets forth all of the requirements that must be met in order to be covered by that claim. Thus, it is not necessary to look at any other claim to determine what an independent claim covers. For example, in this case, claim 1 of each patent is an independent claim. As their name implies, an independent claim must be read independently from the other claims to determine the scope of the claim.

A dependent claim does not itself recite all of the requirements of the claim but refers to another claim or claims for some of its requirements. In this way, the claim “depends” on another claim or claims. A dependent claim incorporates all of the requirements of the claims to which it refers. The dependent claim then adds its own additional requirements. A dependent claim is therefore narrower than an independent claim. Each of the asserted claims are dependent claims. Using the table analogy again, an independent claim would be: Claim 1 – a table comprised of a table top, four legs, and the glue that secures the legs to the tabletop. A dependent claim would be: Claim 2 – the table of claim 1, wherein the table is the color red. While a blue table would be covered by claim 1, a blue table would not be covered by claim 2. Claim 2 is more narrow. To determine what a dependent claim covers, it is necessary to look at both the dependent claim and any other claim or claims to which it refers. So a dependent claim requires all the elements of the claim or claims to which it refers, plus the additional requirement that is specifically set forth in the dependent claim.

### **3.5 “COMPRISING CLAIMS”**

The word “comprising” in a patent claim means “including the following but not excluding others.” A claim that uses the word “comprising” or “comprises” or “including” is not limited to products having only the elements that are recited in the claim, but also covers products that have additional elements.

If you find, for example, that the accused product includes all of the elements of a particular asserted claim, the fact that the accused product also includes additional elements would not avoid infringement of the claim. To use the table example again, a claim covering a table comprising “legs,” “glue,” and “the tabletop” that also has an umbrella still would infringe the claim to a table.

#### **4. PATENT INFRINGEMENT**

##### **4.1 INFRINGEMENT GENERALLY**

I will now instruct you on the rules you must follow when deciding whether Jazz has proven by a preponderance of the evidence that Avadel has infringed the asserted claims.

Infringement is assessed on a claim-by-claim basis. You must compare each asserted claim separately against Avadel's Lumryz product to determine whether the accused product contains all elements of that individual patent claim. You must apply these principles—and those which I will describe further now—to determine whether Jazz has proven infringement of the asserted claims by a preponderance of the evidence.

## **4.2 DIRECT INFRINGEMENT**

Jazz contends that Avadel infringes the asserted claims.

In order to prove infringement, Jazz must prove by a preponderance of the evidence that Avadel made a product, used a product, offered to sell a product, or sold a product that meets all of the elements of any one claim. Infringement requires comparing products to the claims, not the specification.

Deciding whether a claim has been infringed is a two-step process. The first step is to decide the meaning of the patent claim. I have already made this decision and I have already instructed you as to the meaning of some terms of the asserted claims. The second step is to decide whether the party accused of infringement has made, used, sold, offered for sale or imported within the United States an accused product covered by an asserted claim of the patents-in-suit.

To decide whether Avadel's LUMRYZ<sup>TM</sup> product infringes an asserted claim, you must compare that product with the patent claim and determine whether every element (or as they are so called, limitation) of the claim is included. If so, then Avadel's LUMRYZ<sup>TM</sup> product infringes or did infringe that claim. If not, then the accused product does not infringe that claim.

You must determine, separately for each asserted claim, whether or not there is any infringement. The presence of other features in the accused product beyond the claimed elements does not avoid infringement, as long as every claimed element is present.

For direct infringement, Jazz is not required to prove that Avadel intended to infringe or knew of the '488 patent. Whether or not Avadel knew that the accused product infringed or even knew of the '488 patent does not matter in determining direct infringement. Instead, all that matters is whether Avadel's LUMRYZ product is covered by the asserted claims of the '488 patent.

The fact that an accused infringer has its own patent on the accused product does not, on its own, constitute a defense to infringement of someone else's patent. A patent grants only the

right to exclude others. A patent confers no right on its holder to make, use, or sell a product that infringes someone else's patent. The existence of Avadel's patents is relevant to Avadel's defenses and its theories of written description, enablement, improper inventorship, and derivation.

## **5. INVALIDITY**

### **5.1 INVALIDITY GENERALLY**

I will now instruct you on the rules that you must follow in deciding whether or not Avadel has proven that the asserted claims of the patents-in-suit are invalid.

As I previously told you, to prove that a claim of a patent is invalid, the party challenging the validity must persuade you by clear and convincing evidence. The law presumes that the patent claims are valid. The law presumes that the Patent Office acted correctly in issuing the patent. Each of the asserted claims is presumed valid independently of the validity of each other claim. Nevertheless, when the validity of a patent has been put at issue as part of patent litigation, it is the responsibility of the jury to review what the Patent Office has done consistent with the Court's instructions on the law. However, the fact that a patent application is rejected or amended before the patent is issued has no bearing on its ultimate validity.

You should consider whether any evidence relating to invalidity is materially new compared to the evidence considered by the U.S. Patent and Trademark Office ("USPTO"). Where the USPTO did not previously have all the material facts before it, Avadel's burden to prove invalidity by clear and convincing evidence may be easier to sustain.

Like infringement, you must determine whether each asserted claim is invalid on a claim-by-claim basis, with the exception of Avadel's contentions that the patents are invalid for improper inventorship and/or derivation, which are determined on a patent-by-patent basis.

As I instructed you earlier, there are independent claims and dependent claims in a patent. Finding the broader independent claim to be invalid does not mean the narrower dependent claims are also invalid. However, if you find a narrower claim to be invalid, you must find the broader independent claim from which it depends is also invalid.

Claims are construed in the same way for determining infringement as for determining invalidity. You must apply the claim language consistently and in the same manner for issues of infringement and for issues of invalidity.

## **5.2 PERSPECTIVE OF ONE OF ORDINARY SKILL IN THE ART**

The question of invalidity of a patent claim is determined from the perspective of a person of ordinary skill in the art in the field of the invention at the time the invention was made. You may have heard the phrase “person of ordinary skill in the art” abbreviated as “P-O-S-A” or “POSA” throughout the trial.

In this case, the parties agree that a person of ordinary skill in the art would have had a doctorate degree (Ph.D. or Pharm.D.) in pharmaceutical sciences or a related field and around one year of relevant experience, a Master’s Degree with 3-5 years of experience in the pharmaceutical or related industries, or a Bachelor’s degree with 6-10 years of experience in the pharmaceutical or related industries. A POSA would typically have been a member of an inter-disciplinary team of ordinarily skilled scientists involved in drug research and development and would have had direct access to other scientists with ordinary skills in, among other things, pharmacokinetics, pharmacodynamics, drug delivery, and other pharmaceutical characteristics. The team would also have included or had access to an ordinarily skilled individual with a medical degree with experience in treating sleep disorders, particularly of narcolepsy.



### **5.3 WRITTEN DESCRIPTION**

The patent law contains certain requirements for the part of the patent called the specification. The written description requirement is designed to ensure that the inventor invented the claimed subject matter and was in possession of the full scope of claimed invention as of the patent's effective filing date. Avadel contends that the three asserted claims are invalid because the respective patent specifications do not contain an adequate written description of the invention.

To succeed with respect to claims 7 and 11 of the 488 patent, Avadel must show by clear and convincing evidence that a person having ordinary skill in the field reading the 488 patent specification as of the filing priority date of the 488 patent would not have recognized that it describes the full scope of the inventions as they are finally claimed in asserted claims 7 and 11 of the 488 patent. To succeed with respect to claim 24 of the 782 patent, Avadel must show by clear and convincing evidence that a person having ordinary skill in the field reading the 782 patent specification as of the filing priority date of the 782 patent would not have recognized that it describes the full scope of the invention as it is finally claimed in asserted claim 24 of the 782 patent. If a patent claim lacks adequate written description, it is invalid.

In deciding whether the patent satisfies this written description requirement, you must consider the description from the viewpoint of a person having ordinary skill in the field of technology of the patent as of the effective filing date. The specification must describe the full scope of the claimed invention, including each element thereof, either expressly or inherently. A claimed element is disclosed inherently if a person having ordinary skill in the field as of the effective filing date would have understood that the element is necessarily present in what the specification discloses. It is not sufficient that the specification discloses only enough to make the claimed invention obvious to the person having ordinary skill.

The written description does not have to be in the exact words of the claim. The requirement may be satisfied by any combination of the words, structures, figures, diagrams, formulas, etc., contained in the patent specification. Adequate written description does not require either examples or an actual reduction to practice of the claimed invention(s). It is not necessary to describe every compound used in the claimed composition by name or structure in order to satisfy the written description requirement as applied to a group of compounds, as long as the patent includes a sufficient number of representative compounds or a common structural feature, such that a person of ordinary skill in the art would understand, from reading the patent, that the inventor invented the full scope of the claimed invention. However, a mere wish or plan for obtaining the claimed invention(s) is not adequate written description. Rather, the level of disclosure required depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and other considerations appropriate to the subject matter.

During the patent application process, the applicant may keep the originally filed claims, or change the claims between the time the patent application is first filed and the time a patent is issued. An applicant may amend the claims or add new claims provided there is sufficient support in the specification for any added claims. The written description requirement ensures that the issued claims correspond to the scope of the written description that was provided in the original application.

The hallmark of written description is disclosure, which is an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. It is unnecessary to spell out every detail of the invention in the specification, and specific examples are not required; only enough must be included in the specification to convince persons of ordinary

skill in the art that the inventor possessed the full scope of the invention. However, written description support for the essential elements of the invention must be disclosed in the specification itself, and not merely present in the prior art. Claims may be no broader than the supporting disclosure, and a narrow disclosure will limit claim breadth.

#### **5.4 ENABLEMENT**

A patent must disclose sufficient information to enable or teach persons of ordinary skill in the field of the invention to make and use the full scope of the claimed invention without undue experimentation. This requirement is known as the enablement requirement. If a patent is not enabled, it is invalid.

Avadel contends that each of the asserted claims is invalid for lack of enablement. To succeed with respect to the asserted claims of the 488 patent, Avadel must show by clear and convincing evidence that the 488 patent specification does not contain a sufficiently full and clear description to have allowed a POSA to make and use the full scope of the claimed inventions without undue experimentation. To succeed with respect to claim 24 of the 782 patent, Avadel must show by clear and convincing evidence that the 782 patent specification does not contain a sufficiently full and clear description to have allowed a POSA to make and use the full scope of the claimed invention without undue experimentation. The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be “unduly extensive.” Some amount of experimentation to make and use the invention is allowable. In deciding whether a person having ordinary skill would have to experiment unduly in order to make and use the invention, you may consider several factors, including:

- 1) The time and cost of any necessary experimentation
- 2) How routine any necessary experimentation is in the field
- 3) The presence or absence of working examples in the patent
- 4) The amount and sufficiency of guidance presented in the patent
- 5) The nature and predictability of the field
- 6) The level of ordinary skill in the field; and
- 7) The breadth of the claims.

The above list of factors are neither mandatory nor exclusive, and no one or more of the above factors is alone conclusive. Rather, you must make your decision about whether or not the degree of any required experimentation is undue based upon all of the evidence presented to you. You should weigh these factors, and any other evidence related to this issue, and determine whether or not, in the context of this invention and the state of the art at the time of the applicable effective filing date, a POSA would need to experiment unduly to make and use the full scope of the claimed invention claimed in the Asserted Patents.

In considering whether a patent complies with the enablement requirement, you must keep in mind that patents are written for persons of ordinary skill in the field of the invention. Thus, a patent need not expressly state information that persons of ordinary skill would be likely to know or could obtain, such as what was well known in the art and what would have already been available to the public. In addition, the patent disclosure need not enable persons of ordinary skill to make a commercially viable product or to otherwise meet the standards for success in the commercial marketplace.

## **5.5 INVENTORSHIP**

Avadel contends that the '488 and '782 patents are invalid because of improper inventorship.

Patents must name all of the true inventors, and only the true inventors, of the patent. This is known as the inventorship requirement. To prove invalidity of a patent because of improper inventorship, Avadel must demonstrate by clear and convincing evidence that the patent does not name all of the true inventors, or names inventor(s) who are not true inventor(s). In determining whether the inventorship requirement has been satisfied here, you should be guided by the following principles.

To be an inventor, one must make a significant contribution to the conception of at least one of the claims of the patent. Conception is the mental formulation and disclosure by the inventor of a complete idea of the inventive solution. An inventive solution is considered to be a complete idea when disclosure of the idea would enable anyone with ordinary skill in the art to make, use, or practice the invention. Whether the contribution is significant is measured against the scope of the full invention.

All inventors, even those who contribute to only one claim or one aspect of one claim of a patent, must be listed on that patent. Failure to name a true inventor of any claim invalidates the entire patent. For example, if Avadel proves that the actual inventor of any claim of the '488 patent is not named as an inventor, then all of the claims of the '488 patent are invalid for improper inventorship.

In making the determination whether the patents-in-suit are invalid for lack of proper inventorship, you must consider each patent in its entirety and any related evidence and testimony. However, testimony alone is insufficient to support a claim for improper inventorship. A claim for improper inventorship must be supported by corroborating evidence. This corroborating

evidence can include physical, documentary, or circumstantial evidence, or reliable testimony from individuals other than the interested party.

## **5.6 DERIVATION**

Avadel contends that the asserted claims of the '488 patent are invalid because the inventors named on those patents “derived” the subject matter at issue in those patents from another person. Avadel does not assert this defense against the '782 patent.

The patent laws require that the inventors named on a patent be the true inventors of the invention covered by the patent claims. Inventors named on a patent are not the true inventors if they derived the invention from someone else. Avadel must prove this defense by clear and convincing evidence.

In determining whether the inventors derived the invention from someone else, you should be guided by the following principles.

An invention is said to be “derived” from another person if that other person or other people (1) conceived of the patented invention and (2) communicated that conception to one of the inventors named in the patent. Conception of an invention occurs when a person has formed the idea of how to make and use every aspect of the patented invention, and all that is required is that it can be made, without the need for further inventive effort. Communication of the conception occurs when it enables one of ordinary skill in the art to make, use, and practice the patented invention. The communication may be made via public disclosure. If the named inventors derived the patented invention from someone else, then the patent is invalid.



## **6. PATENT DAMAGES**

### **6.1 DAMAGES INTRODUCTION**

All the instructions that I have given you up to this point have been about determining liability, meaning the determination as to whether Avadel has infringed the asserted claims of Jazz's patents and whether those asserted claims are valid. If you find that Avadel infringed any valid claim of the asserted patents, you must then consider what amount of damages to award to Jazz for Avadel's past infringement. If you find that each of the asserted claims is either invalid or not infringed, then you should not consider damages in your deliberations. I will instruct you now on how to determine the amount of damages, if any. By instructing you on damages, I am not suggesting which party should win this case, on any issue.

There is no requirement that Jazz make, use, or sell its patented invention for damages to occur. If you find Avadel infringed, the damages you award must be adequate to compensate Jazz for the infringement, and Jazz is in any event entitled to no less than a reasonable royalty.

Damages are not meant to punish an infringer.

Jazz has the burden to establish the amount of its damages, by a preponderance of the evidence. In other words, you should award those damages that Jazz establishes that it more likely than not has suffered. Jazz must prove the amount of damages with reasonable approximation under the circumstances, but need not prove the amount of damages with mathematical precision.

Even if the evidence at trial does not support one or both parties specific royalty calculation, you are still required to determine what reasonable royalty if any, is supported by the evidence.

Jazz seeks damages for Avadel's past patent infringement as measured by a reasonable royalty. A reasonable royalty is defined as the money amount the parties would have agreed upon as a fee for use of the invention at the time prior to when infringement began.

I will now give you more detailed instructions regarding damages.

## **6.2 DATE DAMAGES BEGIN**

The parties agree that Avadel imported LUMRYZ<sup>TM</sup> into the United States no earlier than May 17, 2023 and began selling LUMRYZ<sup>TM</sup> by June 2, 2023. Thus, if you find that the asserted patents are valid and infringed, you should calculate damages beginning as of the May-June 2023 timeframe.

### **6.3 REASONABLE ROYALTY – GENERALLY**

Jazz is seeking damages in the form of a reasonable royalty in this case.

A royalty is a payment made to a patent owner by someone else in exchange for the rights to make, use, sell, or import a patented product. A reasonable royalty is the royalty that would have resulted from a hypothetical negotiation between the patent owner and the alleged infringer just before the alleged infringement began. It is a hypothetical royalty for the use of the patented technology by the alleged infringer, calculated as if the parties negotiated at arm's length as a willing licensor and a willing licensee on the date when the infringement began. A reasonable royalty award should reflect the incremental value that the patented invention adds to the end product as a whole. When the infringing products have both patented and unpatented features, measuring this value requires a determination of the value added by the patented features. The total royalty rate must reflect the value attributable to the infringing features of the product, and no more.

In considering this hypothetical negotiation, you should focus on what the expectations of the patent owner and the infringer would have been if they had entered into an agreement at that time, and had they both acted reasonably in their negotiations. You must assume that both parties to the hypothetical negotiation believed the patent to be valid and infringed and that both parties are willing to enter into a license agreement just before the infringement began.

Having that in mind, you should consider all the facts known and available to the parties at the time the infringement began. The reasonable royalty must be a royalty that would have resulted from the hypothetical negotiation, and not simply a royalty either party would have preferred.

#### **6.4 FACTORS FOR DETERMINING REASONABLE ROYALTY**

In determining a reasonable royalty, you should consider evidence on any of the following factors, in addition to any other evidence presented by the parties on the economic value of the patents-in-suit:

1. Any royalties received by Jazz for the licensing of the patents- in-suit, proving or tending to prove an established royalty;
2. The rates paid by Avadel to license other patents comparable to the patents-in-suit;
3. The nature and the scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold;
4. Jazz's established policy and marketing program to maintain its patent exclusivity and its right to exclude others from using the patented inventions by not licensing others to use the invention, or by granting licenses under special conditions designed to preserve that exclusivity;
5. The commercial relationship between Jazz and Avadel at the time of the hypothetical negotiation, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter;
6. The effect of selling the patented product in promoting sales of other products of Avadel, the existing value of the invention to the Jazz as a generator of sales of its non-patented items, and the extent of such collateral sales;
7. The remaining life of the patents-in-suit and the terms of the hypothetical license;
8. The established profitability of the products made under the patents-in-suit, their commercial success, and their current popularity;

9. The utility and advantages of the patented invention over the old modes or devices, if any, that had been used for achieving similar results;
10. The nature of the patented invention, the character of the commercial embodiment of it as owned and produced by Jazz, and the benefits to those who have used the invention;
11. The extent to which Avadel has made use of the invention, and any evidence probative of the value of that use;
12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions;
13. The portion of the realizable profit that should be credited to the inventions as distinguished from non-patented features, the manufacturing process, business risks, or significant features or improvements added by Avadel;
14. The opinion and testimony of qualified experts; and
15. The amount that Jazz as the patent owner and Avadel would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee – who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention – would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a patentee who was willing to grant a license.
16. Any other economic factor that a normally prudent businessperson would, under similar circumstances, take into consideration in negotiating the hypothetical

license. This may include the absence of commercially acceptable, non-infringing alternatives at the time of the hypothetical negotiation.

No one of these factors is dispositive, and you can and should consider the evidence that has been presented to you on each of these factors. You may also consider any other factors that would have increased or decreased the royalty that Avadel would have been willing to pay and that Jazz would have been willing to accept.

**6.5 REASONABLY ROYALTY – NON-INFRINGEMENT  
ALTERNATIVES OR SUBSTITUTES**

In determining a reasonable royalty, you may also consider evidence concerning the absence of acceptable non-infringing alternatives to using the patented invention. A non-infringing alternative must have been available at the time of the infringement, must provide the same advantages as the patented invention, must have been acceptable to the specific purchasers of the infringing products, not the public in general, and must not infringe the patent.

## **6.6 REASONABLY ROYALTY – TIMING**

The relevant date for the hypothetical negotiation is at the time the infringement began. However, you may also consider in your determination of reasonable royalty any information the parties would have foreseen or estimated during the hypothetical negotiation, which may under certain circumstances include evidence of usage after infringement started, license agreements entered into by the parties shortly after the date of the hypothetical negotiation, profits earned by the infringer, and non-infringing alternatives.



## **6.7 PATENT DAMAGES INTEREST**

Neither party's calculations include interest. Therefore, in arriving at your damages calculation, you should not consider interest in any way because it is the function of the Court to award interest.

## **7. DELIBERATION AND VERDICT**

### **7.1 INTRODUCTION**

I have concluded the part of my instructions explaining the rules for considering some of the testimony and evidence. Now let me finish up by explaining some things about your deliberations in the jury room, and your possible verdicts.

Once you start deliberating, do not talk to the jury officer, or to me, or to anyone else except each other about the case. If you have any questions or messages, you must write them down on a piece of paper, sign them, and then give them to the jury officer. The officer will give them to me, and I will respond as soon as I can. I may have to talk to the lawyers about what you have asked, so it may take some time to get back to you. Any questions or messages normally should be sent to me through your foreperson, who by custom of this Court is Juror No. 1.

One more thing about messages. Do not ever write down or tell anyone how you stand on your votes. For example, do not write down or tell anyone that you are split 4-4, or 6-2, or whatever your vote happens to be. That should stay secret until you are finished.

## **7.2 UNANIMOUS VERDICT**

Your verdict must represent the considered judgment of each juror. In order for you as a jury to return a verdict, it is necessary that each juror agree to the verdict. Your verdict must be unanimous.

It is your duty, as jurors, to consult with one another and to deliberate with a view towards reaching an agreement, if you can do so without violence to your individual judgment. Each of you must decide the case for yourself, but do so only after an impartial consideration of the evidence with your fellow jurors. In the course of your deliberations, do not hesitate to reexamine your own views and change your opinion, if convinced it is erroneous. But do not surrender your honest conviction as to the weight or effect of evidence solely because of the opinion of your fellow jurors, or for the purpose of returning a verdict. Remember at all times that you are not partisans. You are judges—judges of the facts. Your sole interest is to seek the truth from the evidence in the case.

A form of verdict has been prepared for you. I will review it with you in a moment. You will take this form to the jury room and when you have reached unanimous agreement as to your verdict, you will have your foreperson fill in, date and sign the form. You will then return to the Courtroom and my deputy will read aloud your verdict. Place the completed verdict sheet in the envelope we will give you. Do not show the completed verdict form to anyone or share it with anyone until you are in the Courtroom.

It is proper to add the caution that nothing said in these instructions, and nothing in the verdict form, is meant to suggest or convey in any way or manner any intimation as to what verdict I think you should find. What the verdict shall be is your sole and exclusive duty and responsibility.

### **7.3 DUTY TO DELIBERATE**

Now that all the evidence is in and the arguments are completed, you are free to talk about the case in the jury room. In fact, it is your duty to talk with each other about the evidence, and to make every reasonable effort you can to reach unanimous agreement. Talk with each other, listen carefully and respectfully to each other's views, and keep an open mind as you listen to what your fellow jurors have to say. Try your best to work out your differences. Do not hesitate to change your mind if you are convinced that other jurors are right and that your original position was wrong. But do not ever change your mind just because other jurors see things differently, or just to get the case over with. In the end, your vote must be exactly that—your own vote. It is important for you to reach unanimous agreement, but only if you can do so honestly and in good conscience.

No one will be allowed to hear your discussions in the jury room, and no record will be made of what you say. So you should all feel free to speak your minds.

Listen carefully to what the other jurors have to say, and then decide for yourself.

#### **7.4 SOCIAL MEDIA**

During your deliberations, you must not communicate with or provide any information to anyone by any means about this case. You may not use any electronic device or media, such as the telephone, a cell phone, smartphone, iPhone, Blackberry, tablet or computer, the Internet, any Internet service, any text or instant messaging service, any Internet chat room, blog or website such as Facebook, LinkedIn, YouTube, Instagram, Snapchat or X to communicate to anyone any information about this case or to conduct any research about this case until I accept your verdict. In other words, you cannot talk to anyone on the phone, correspond with anyone, or electronically communicate with anyone about this case. You can only discuss the case in the jury room with your fellow jurors during deliberations.

**7.5 COURT HAS NO OPINION**

Let me finish by repeating something I said to you earlier. Nothing that I have said or done during this trial was meant to influence your decision in any way. You must decide the case yourselves based on the evidence presented.